

From: [Bill Jacobs](#)
To: [Denise Keyes](#)
Bcc: [Dan Peacock](#); [Jennifer Gaines](#)
Subject: RE: Rodent Bait Stations
Date: 01/19/2010 12:05 PM

The reports must be submitted to us in the format outlined in PR Notice 86-5. It's an-EPA/OPP specific format which includes several extra pages of authorizations, statements concerning Good Laboratory Practice Standards (GLPs), and the like. The 86-5 formatting essentially "goes around" the research report and should not affect it substantively. Your client(s) should be familiar with 86-5 formatting and should be expected to add it to what you supply to them. It is not necessary that the report be submitted in electronic format, but it's submission is up to your client(s).

The report that you provide to your client(s) should include all raw data, photographs of the test set-up and of any compromise units, as well as other items mentioned in the protocols. Be sure to describe the unit(s) tested in sufficient detail that it is clear which specific design was tested.

▼ "Denise Keyes" ---01/15/2010 01:52:48 PM---Thank you for the information. Do you have a format for reports that you would like us to use when

From: "Denise Keyes" <denise@crr.net>
To: Bill Jacobs/DC/USEPA/US@EPA
Date: 01/15/2010 01:52 PM
Subject: RE: Rodent Bait Stations

Thank you for the information. Do you have a format for reports that you would like us to use when submitting the test data? Does it need to be sent in electronic format?

Thanks
Denise Keyes

-----Original Message-----
From: Jacobs.Bill@epamail.epa.gov
[mailto:Jacobs.Bill@epamail.epa.gov]
Sent: Thursday, January 14, 2010 12:51 PM
To: Denise Keyes
Cc: Parsons.Laura@epamail.epa.gov
Subject: Re: Rodent Bait Stations

For the adult-use test, the sex ratio has been revised to 50:50 with approximately equal distribution across the 18-70 years age range (e.g., 20 males and 20 females ages 18-38 years, 20 males and 20 females ages 39-59 years, and 10 males and 10 females ages 60-70 years.

The levels of effectiveness remain as indicated in the protocol versions that were attached to the 2008 Rodenticide Risk Mitigation Decision. The higher percent success (non-failure) for the first 50 subjects in the child test is based upon a statistical model which indicates that,

if there are only 2 failures over the first 50 subjects, the product under test would be extremely unlikely to fail if tested with the full complement of 200 children aged 42-51 months.

"Child-resistance" is an index used to assess the safety of closed packages. As applied to rodenticide bait stations, "tamper-resistance" addresses a station's suitability when evaluated against the 8 criteria indicated in PR Notice 94-7. One aspect of those criteria is the station's ability to isolate bait from young children. Protocol 1.229 is used to assess that component of tamper-resistance. In contrast to containers used in child-resistant packaging tests, rodenticide bait stations are tested with children in an "open" condition, in the sense that the passages which make bait accessible to rodents are not closed off for child testing.

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| "Denise Keyes" <denise@crr.net>
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| Bill Jacobs/DC/USEPA/US@EPA
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| Rodent Bait Stations
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Dear Bill:

I spoke to you last July regarding the testing of rodent bait stations.
You indicated that the OPP Designation 1.228 and 1.229 are the current protocols for these types of stations and that the test panels should consist of panels of 50 children, aged 42-51 months and 100 adults, aged 18-70. I have a few questions regarding this testing.

How should the adult ages be allocated for the testing if we are using a panel aged 18-70?

In the OPP Designation it mentions that the adult participants should consist of 70% female. Is this correct or should the male/female be allocated equally?

Are the effectiveness levels listed in the protocol correct?
(90% for the adults and 85% for a 200 child study - or 96% for a 50 child study)
What is the difference between child-resistance and tamper-resistance for these bait stations?

Thank you for your assistance with these questions.

Kindest regards,

Denise Keyes
Child Related Research, Inc.

Internal Virus Database is out of date.
Checked by AVG - www.avg.com
Version: 8.5.425 / Virus Database: 270.14.67/2505 - Release
Date: 11/15/09
19:50:00